This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: _____ MAY - 5 2004

510(k) number: K040641

Applicant Information:
Epicor Medical, Inc.
240 Santa Ana Court
Sunnyvale, CA 94085-4512

Contact Person
Kathi M. Guerrant
Phone Number: (408) 733-6500
Fax Number: (408) 733-6682

Device Information:

Classification:	Unclassified
Trade Name:	Epicor Medical UltraCinch Tissue Ablation Device and Accessories
Classification Name:	Ultrasonic Surgical Instruments

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the Epicor Medical UltraWand tissue ablation device (K022894), the Medtronic Cardioblate Radiofrequency Ablation System (K013392), the Boston Scientific Cobra RF and Cooled RF Family of Surgical Probes (K013873, K023291), the AFx Microwave Ablation System (K003978, K013946), and the CardioFocus Surgical Lightstic (K011988, K013901).

Intended Use:
The Epicor Medical UltraCinch is intended for the ablation of cardiac tissue during cardiac surgery.

The items in the UltraCinch Accessory Pack are intended for use in the ablation of cardiac tissue during cardiac surgery.

Test Results:
Performance
Results of *in vitro* testing, *in vivo* testing, and human clinical studies demonstrate that the Epicor Medical UltraCinch tissue ablation device and accessories are safe and effective for their intended use.

Biocompatibility
The materials used in the Epicor Medical UltraCinch tissue ablation device and accessories meet the requirements of ISO 10993-1.

Summary: Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Epicor Medical, Inc.
c/o Ms. Kathi Guerrant
V. P., Regulatory Affairs and Quality Assurance
1635 Energy Park Drive
St. Paul, MN 55108

Re: K040641
Trade Name: Epicor Medical UltraCinch Tissue Ablation Device and Accessories
Regulation Number: Unknown
Regulation Name: Unknown
Regulatory Class: Unclassified
Product Code: LFL
Dated: March 09, 2004
Received: March 10, 2004

Dear Ms. Guerrant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040641

Device Name: **Epicor Medical UltraCinch Tissue Ablation Device and Accessory Pack**

Indications For Use:

The Epicor Medical UltraCinch is intended for the ablation of cardiac tissue during cardiac surgery.

The items in the UltraCinch Accessory Pack are intended for use in the ablation of cardiac tissue during cardiac surgery.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ashley B. Boam

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040641